CAUTION: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp. Do not get in eyes. Follow instructions carefully and wash hands thoroughly after each use.

(e) *Exemption for certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: March 27, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019–06238 Filed 3–29–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 806

**[Docket No. FDA–2019–N–1345]**

## Medical Devices; Technical Amendment

**AGENCY:** Food and Drug Administration; HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is amending the medical device reports of corrections and removals regulation to correct three inaccurate cross-references. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

**DATES:** This rule is effective April 1, 2019.

**FOR FURTHER INFORMATION CONTACT:** Madhusoodana Nambiar, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5518, Silver Spring, MD 20993–0002, 301–796–5837.

**SUPPLEMENTARY INFORMATION:** FDA is amending 21 CFR 806.1 to correct three inaccurate cross-references to ensure accuracy and clarity in the Agency's medical device regulations regarding medical device reports of corrections and removals. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulation is nonsubstantive and provides only technical changes to correct inaccurate cross-references.

In the **Federal Register** of September 24, 2013 (78 FR 58821), FDA added the definition of ''*Human cells, tissues, or cellular or tissue-based product (HCT/P) regulated as a device*'' at § 806.2(f). The addition of this definition caused the paragraphs following paragraph (f) in § 806.2 to be redesignated alphabetically. Although the definitions of the terms were correct in § 806.2, the paragraphs in § 806.1(b) cross-referenced three of the definitions (market withdrawal, routine servicing, and stock recovery) from § 806.2 based on the previous designations.

### List of Subjects in 21 CFR Part 806

Imports; Medical devices; Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 806 is amended as follows:

## PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

■ 1. The authority citation for part 806 continues to read as follows:

**Authority:** 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 2. In § 806.1, revise paragraphs (b)(2) through (4) to read as follows:

**§ 806.1 Scope.**

* * * * *

(b) * * *

(2) Market withdrawal as defined in § 806.2(i)

(3) Routine servicing as defined in § 806.2(l).

(4) Stock recovery as defined in § 806.2(m).

Dated: March 26, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019–06139 Filed 3–29–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 866

**[Docket No. FDA–2011–N–0103]**

**RIN 0910–AH98**

## Microbiology Devices; Classification of In Vitro Diagnostic Devices for Bacillus Species Detection

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to classify in vitro diagnostic devices for *Bacillus* species (spp.) detection into class II (special controls) and to continue to require a premarket notification (510(k)) to provide a reasonable assurance of safety and effectiveness of the device. FDA is also establishing special controls in a special controls guideline in addition to restricting use and distribution of the devices. An in vitro diagnostic device for *Bacillus* spp. detection is a prescription device used to detect and differentiate among *Bacillus* spp. and presumptively identify *B. anthracis* and other *Bacillus* spp. from cultured isolates or clinical specimens as an aid in the diagnosis of anthrax and other diseases caused by *Bacillus* spp.

**DATES:** This rule is effective May 1, 2019. See further discussion in section V ''Implementation Strategy''.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beena Puri, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4502, Silver Spring, MD 20993–0002, 301–796–6202. *Beena.Puri@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### Table of Contents